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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

August 12, 1998

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-20-98W

Mr. David Parker, President
North Atlantic Imaging Systems, Inc.
49 Lower East Street, #3
Dedham, MA 02026

Dear Mr. Parker:

On July 17, 1998, Investigator George T. Allen of the Food & Drug Administration (FDA) performed a field test of a certified diagnostic x-ray system which your firm assembled [redacted] according to Form FDA 2579, Report of Assembly of a Diagnostic X-ray System, [redacted] The system was tested to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (Title 21, Code of Federal Regulations (CFR), sections §1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). This field test, Test ID [redacted], was performed at:

[redacted]

This letter also confirms Mr. Michael Leal's telephone notification to you on July 31, 1998, regarding the serious noncompliance of this system with the performance standard and his request that you immediately correct this violation. Additionally, we are in receipt of a facsimile notification from Mr. Tom Graziano of your firm to Mr. Michael Leal, X-ray Auditor, of our Worcester office, stating that appropriate corrective actions have been taken.

- X-ray production was possible when the primary protective barrier (PPB) was not in position to intercept the entire useful beam. 21 CFR §1020.32(a) requires that x-ray production be prohibited until the primary protective barrier is in position to intercept the entire useful beam. This condition is a serious radiation health hazard and warrants your immediate attention.

Our analysis of the field test data indicates that the system does not comply with the following, additional items of the performance standard:

- The absolute sum of the percent deviations of the length and width for the spot film selected size of [redacted] was calculated to be [redacted] of the source to image distance [redacted] 21 CFR §1020.31(h)(2) requires that the sum, without regard to sign, of the length and width differences not exceed 4 percent of the SID.

In addition to the above problems, we consider the compliance status of the following items to be suspect. Please verify the compliance status of these items when you correct the previously cited problems.

- The length and width of the x-ray field differed from the selected spot film size of [redacted] at a source to image distance of [redacted] percent of the SID in both directions. 21 CFR §1020.31(h) requires that neither the length nor width of the x-ray field exceed the selected corresponding dimensions of the spot film device by more than 3 percent of the SID.

- On the above table collimator the x-ray field dimension differs from that indicated on the collimator b[redacted]t along the table an[redacted] across the table at a[redacted] source-image distance (SID) for an indicated field size [redacted] 1 CFR §1020.31(e)(3) requires that for radiographic equipment, each field dimension shall not differ from that indicated by more than 2 percent of the SID.

We request that you, as the responsible assembler, immediately investigate the deviations from the performance standard cited above in accordance with 21 CFR §1003 and §1004 as follows:

1. If you determine that the noncompliances and/or defects are caused by improper assembly or installation, you must correct the noncompliances and/or defects at no charge to the user by either repairing the system, replacing it, or refunding the cost.

2. If you determine that the noncompliances and/or defects are caused by the factory-based manufacturer, you must notify him of the noncompliances and/or defects and send documentation of such notification to this office.

3. If you can establish that the system is compliant, that the alleged deviation or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR §1003.30 within fifteen (15) days of receipt of this letter.

You must report the results of your investigation and follow-up actions to this office within fifteen (15) days of receipt of this letter. Your response should include the date that the corrective action was completed and copies of service records and/or other supportive documents. If you do not respond within fifteen (15) days, the FDA may consider you to be in violation of the Federal Food, Drug, and Cosmetics Act (the Act) sections 538(a)(2) and 538(a)(4) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Please note that improper installation, including failure to follow installation instructions which cause the system to be noncompliant with the Performance Standard may cause the system to be adulterated. Under 501(c) of the act the system would not be of a quality represented by the labeling (including the certification statement).

Failure to promptly correct this violation can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided for in section 539 of the Act. Persons violating section 538 of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Alyson L. Saben, Compliance Officer, U.S. Food and Drug Administration, New England District Office, One Montvale Avenue, Stoneham, MA 02180. If you have any questions, please contact Ms. Saben at 781-279-1675, Extension 120.

Sincerely,

John R. Marzilli
District Director
New England District Office

cc: [redacted]

Robert Hallisey, Director
Radiation Control Program
174 Portland Street, 5th Floor
Boston, MA 02114

[redacted]